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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,766

03/22/2004

Jacob Fraden

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EXAMINER

BERHANU, ETSUB D

ART UNIT

PAPER NUMBER

3768

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/806,766	<b>Applicant(s)</b> FRADEN, JACOB	
	<b>Examiner</b> ETSUB D. BERHANU	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-24 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/5/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Objections***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 1-19 have been renumbered 6-24.

3. Claims 14, 15 and 18-20 are objected to because of the following informalities: the term “being” in line 3 of claim 14 should be deleted; the term "oxigenation" in claims 18-20 should be amended to read - - oxygenation - -; claim 15 should be amended to add the term - - a - - between the terms “comprising” and “processing” in line 1. Appropriate correction is required.

#### ***Election/Restrictions***

4. Newly submitted claims 21-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original claims were directed towards a system and method for detecting blood oxygenation measurements from an ear canal, classified in class 600, subclass 340. Claim 21 is directed towards a method of monitoring arterial blood pressure from a patient's ear canal, classified in class 600, subclass 480. Claims 22-24 are directed towards a separate embodiment of the originally claimed invention, claims 22-24 being directed towards a sensor for

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simultaneously monitoring blood oxygenation and subcutaneous temperature from skin of a patient, wherein the sensor comprises a first temperature sensor capable of being thermally coupled to the skin of a patient.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Specification does not disclose a protective cover fabricated of pliable film which is adapted for enveloping a portion of an extension, wherein the film is substantially transparent for light emitted by a light source.

***Claim Rejections - 35 USC § 102***

7. Claims 6-11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulze et al.'692 (previously cited).

Schulze et al.'692 discloses a vital signs sensing assembly 76 for monitoring blood oxygenation from a patient's ear canal (see ABSTRACT), the assembly comprising in combination: a probe (Figure 6,

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element 86) adapted for positioning outside of the patient's ear canal; an ear plug (Figure 6, element 78) fabricated of a pliable and resilient material (col. 7, lines 13-18) and having a proximal end and a distal end, wherein the distal end is adapted for insertion into the patient's ear canal and the proximal end is connected to the probe by means of an extension (Figure 6, element 82), wherein a proximal end of the extension is connected to the probe and a distal end of the extension is adapted for insertion into the patient's ear canal; wherein the distal side of the extension contains at least one light transmitting window (Figure 10, element 112) for passing light from a light emitting source (Figure 10, element 110); an optical wave guide (Figure 10, element 115); a contact temperature sensor (Figure 10, element 122) at the distal end of the ear plug and thermally coupled with the patient's ear canal; an electrical connector (Figure 10, element 120) between the temperature sensor and the probe; and a processing electronic circuit (Figure 2, element 22) coupled to the probe (see descriptions of Figures 2, 6 and 10).

Schulze et al.'692 further discloses a method for monitoring a patient's arterial blood oxygenation and core body temperature by an ear probe consisting of a housing, ear plug, two light emitting devices, one light detecting device and a temperature detector (see description of sensor above), the method comprising the steps of: attaching a temperature sensor to a flexible ear plug, inserting the ear plug into the patient's ear canal, alternatively transmitting two wavelengths of light to the ear canal and measuring the reflected light, measuring a temperature of the ear plug with the temperature sensor, computing a level of blood oxygenation from signals received from the light detecting device and computing the patient core temperature (col. 3, lines 37-45 and col. 4, line 9 – col. 5, line 24).

***Claim Rejections - 35 USC § 103***

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, as applied to claim 6, further in view of Schulze et al.'852 (previously cited).

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Schulze et al.'692 discloses all the elements of the current invention, as discussed in paragraph 7 above, except for the ear plug being fabricated of a material being substantially transparent for light emitted by the light emitting source. Schulze et al.'852 teaches a pliable, resilient and transparent ear plug that allows visual inspection of internal components (col. 8, lines 53-58). It would have been obvious to one of ordinary skill in the art to modify the ear plug of Schulze et al.'692 to be transparent, as taught by Schulze et al.'852, since it would allow inspection of internal components.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, as applied to claim 6, further in view of Nolan et al.'274 (USPN 6,004,274).

Schulze et al.'692 discloses all the elements of the current invention, as discussed in paragraph 7 above, except for the ear plug having at least one flexible rib positioned on its outer surface between the proximal end and distal end. Nolan et al.'274 teaches the use of a flexible rib (Figure 1, element 16) on an outer surface of an ear plug in order to provide an air tight seal in an individual's ear canal (col. 5, lines 45-55). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the ear plug of Schulze et al.'692 to include a flexible rib, as taught by Nolan et al.'274, since it would help to provide an air tight seal with the ear canal, thus providing a more secure fit.

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, as applied to claim 6, further in view of Gratton et al.'261 (USPN 6,192,261).

Schulze et al.'692 discloses all the elements of the current invention, as discussed in paragraph 7 above, except for the ear plug incorporating a substantially opaque light stopper. Gratton et al.'261 teaches the use of an opaque light stopper situated between light emitting sources and a light detector in order to prevent the direct transmission of light from the light sources to the detector without having had passed through tissue (col. 6, lines 20-26). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the ear plug of Schulze et al.'692 to include a light stopper, as

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taught by Gratton et al.'261, since it would prevent the light not having passed through tissue from reaching the detector, thus providing more accurate measurement results.

11. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692 further in view of Schulze et al.'852.

See rejection set forth in paragraph 8 above.

12. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692 further in view of Schulze et al.'852, as applied to claim 18, further in view of Fraden et al.'405.

Schulze et al.'692 further in view of Schulze et al.'852 discloses all the elements of the current invention, as discussed in paragraph 8 above, except for the method comprising measuring a temperature of the ear probe, generating heat with a heater to minimize a temperature difference and computing a patient core temperature from signals received from temperature sensors. Fraden et al.'405 teaches compensating for a heat lost from the ear canal to the environment with the use of an external temperature sensor and heating element on an ear probe by measuring a temperature of the ear probe with the external temperature sensor and generating heat with a heater to minimize a temperature difference between the internally measured temperature and the externally measured temperature in order to negate a temperature gradient across the plug and produce a patient core body temperature measurement with high accuracy (see ABSTRACT and col. 2, lines 8-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Schulze et al.'692 further in view of Schulze et al.'852 to include measuring a temperature of the ear probe with a temperature detector and generating heat by a heater to minimize a temperature difference, as taught by Fraden et al.'405, since it would produce more accurate patient core body temperature measurements.

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, as applied to claim 6, further in view of Fraden et al.'405 (previously cited).

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Schulze et al.'692 discloses all the elements of the current invention, as discussed in paragraph 7 above, except for the assembly further comprising a heater thermally coupled to the probe. Fraden et al.'405 teaches the use of a heater thermally coupled to a probe in order to compensate for a heat lost from an ear canal to the environment by using the heater to minimize a temperature difference between an internally measured temperature and an externally measured temperature (see ABSTRACT and col. 2, lines 8-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the assembly of Schulze et al.'692 to include a heater thermally coupled to the probe, as taught by Fraden et al.'405, since it would produce more accurate patient core body temperature measurements.

#### ***Response to Arguments***

14. Applicant's arguments with respect to claims 6-20 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768

EDB